

**RULES
OF
THE TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY**

**CHAPTER 0720—3
CERTIFICATE OF NEED PROGRAM—SCOPE AND PROCEDURES**

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0720—3—.01 PRIVATE PROFESSIONAL PRACTICE EXEMPTION¹

- (1) Seeking licensure of a place, building, or facility as a health care institution is inconsistent with an assertion that such place, building, or facility is being occupied “exclusively as the professional practice office” of a medical doctor, osteopath, or dentist. Therefore, any person who seeks licensure as a health care institution as set forth in T.C.A. § 68—11—1602 must secure a certificate of need.
- (2) To establish or maintain a health care institution that does not require licensure, a certificate of need is required unless the place, building, or facility is occupied exclusively as the professional practice of a medical doctor, osteopathic doctor, or dentist. In determining whether the professional practice exemption is met, the Agency may consider all relevant factors, including but not limited to, form of facility ownership, types of service reimbursement sought and/or received, patient referral sources, advertising/marketing efforts, and whether the private practitioner retains complete responsibility for management and business control.²
- (3) The “private professional practice” exemption has no application in regard to initiation of services, acquisition of major medical equipment, or other actions requiring a certificate of need. The applicability of the exemption, as defined above, is limited to the definition of a “health care institution.”

Authority: T.C.A. §§ 68—11—1605; 68—11—1602; 68—11—1607; 4—5—202.

0720—3—.02 ACTIVITIES REQUIRING NOTIFICATION—MISCELLANEOUS PROVISIONS³

- (1) Any nursing home which increases its bed complement pursuant to the ten (10) bed/ten (10)% provision of T.C.A. §68—11—1607⁴ must have the additional beds; licensed within one year of Agency receipt of notice of the increase. If such beds are not licensed within such one (1) year period, the notice shall be void, and the increase in bed complement shall not be implemented.
- (2) Any hospital with fewer than one hundred (100) licensed beds, which increases its bed complement pursuant to the ten (10) bed provision of T.C.A. §68—11—1607 must have the additional beds licensed within one (1) year of Agency receipt of the notice of the increase. If the additional beds are not licensed within such one (1) year period, the notice shall be void, and the increase in bed complement shall not be implemented.
- (3) For purposes of the nursing home ten (10) bed/ten (10)% exemption, and the hospital ten (10) bed exemption, the one (1) year period after which the next such exempted change may be initiated at the facility shall begin on the date when the most recent exempted bed change at the facility is actually licensed. For the purposes of this exemption, “licensed bed capacity” shall mean that number of beds actually licensed in a facility at the time the exempted increase or decrease is initiated.
- (4) Any person claiming the exemption from certificate of need requirements for the acquisition of major medical equipment on the basis that such equipment is a replacement or upgrade of existing equipment,

shall provide notice to the Agency at least sixty (60) days prior to the purchase on a form provided by the Agency, ~~as provided in Rule 0720—5—.03.~~⁵

- (5) Notice of a change of ownership occurring within two (2) years of the date of initial licensure of a health care institution must be provided to the Agency within thirty (30) days of the effective date on forms provided by the Agency, ~~as provided in Rule 0720—5—.04. For purposes of this paragraph, a “change of ownership” is as defined in applicable rules of the Board for Licensing Health Care Facilities.~~⁶
- ~~(6) Registration of ownership of medical equipment including computerized axial tomographers, extracorporeal lithotripters, magnetic resonance imagers, and any other equipment specified by law shall be made with the Agency within ninety (90) days of acquisition of such equipment or within ninety (90) days of October 1, 1993, whichever occurs later. Registration shall be made by use of a form provided by the Agency, as provided in Rule 0720—05.~~⁷

Authority: T.C.A. §§68—11—1605; 68—11—1607; 68—11—1602; 4—5—202.

0720—3—.03 STANDARD PROCEDURES FOR CERTIFICATE OF NEED

- (1) Application Form. Each application will be filed using standard application forms provided by the Agency. The applicant must provide all information requested in the application forms.
- (2) Letters of Intent.
 - (a) Each Letter of Intent shall be filed using standard forms provided by the Agency. The applicant must provide all information requested in the Letter of Intent form.
 - (b) Each Letter of Intent for home care organization applications shall also specify all counties in the proposed service area.
 - (c) Any Letter of Intent which contains insufficient information may be deemed void. The Letter of Intent may be refiled, but it is subject to the same requirements as an original Letter of Intent.
 - (d) Simultaneous with its filing with the Agency, the Letter of Intent shall be published for one day in a newspaper of general circulation in the county where the proposed project is to be located. The Letter of Intent shall be published in the Legal Notice section in a space which should be no smaller than four (4) column inches. Publication must be in the same form and format as the Publication of Intent form provided by the Agency.
 - 1. For the purpose of these rules, “simultaneous” means that publication should, if possible, occur on the same day as filing. A day or two delay between filing and publication will not necessarily void the Letter of Intent, but both filing and publication must occur between the 1st and 10th day of the month preceding the beginning of the review cycle. If the last day for filing the Letter of Intent is a Saturday, Sunday or State holiday, filing must occur on the last preceding regular business day. If both filing and publication do not occur within the time period, the Letter of Intent will be null and void, and the applicant will be notified in writing.
 - 2. For the purpose of these rules, “newspaper of general circulation” means a publication with the following characteristics:
 - (i) is regularly issued at least once a week;
 - (ii) has a ~~second~~third class mailing privilege;⁸
 - (iii) includes a Legal Notice Section;
 - (iv) is not fewer than four (4) pages in length;

- (v) has been published continuously during the immediately preceding one year period;
- (vi) is published for dissemination of news of general interest; and
- (vii) is circulated generally in the county in which it is published.

3. In any county where a publication fully complying with this definition does not exist, the Executive Director is authorized to determine appropriate publication to receive any required Letter of Intent. A newspaper which is engaged in the distribution of news of interest to a particular interest group or other limited group of citizens, is not a "newspaper of general circulation."
4. In the case of an application for or by a home care organization, the Letter of Intent shall be published in each county in which the agency will be licensed or in a regional newspaper which qualifies as a newspaper of general circulation in each county. In those cases where the Letter of Intent is published in more than one newspaper, the earliest date of publication shall be the date of publication for the purpose of determining the date for the timely filing of the application. Both the Letter of Intent and the application must specify the counties to be served.

⁹~~(3) Competing Applications. Those persons desiring to compete for a Certificate of Need for which a Letter of Intent has been filed shall file a Letter of Intent with the Agency and the original applicant, and publish the Letter of intent simultaneously in a newspaper of general circulation, as those terms are defined in sub-paragraph (2)(d), in the same county as the original applicant within ten (10) days after publication by the original applicant. The Executive Director or his/her designee will determine whether application(s) are "competing."~~

~~(a) The competing applicant shall, at the time the Letter of Intent is filed with the Agency also file a verified statement certifying it has complied with the procedural requirements for a competing application.~~

~~(b) In addition to the procedural requirements, the following factors may be considered by the Executive Director in determining whether the applications are competing~~

- ~~1. Similarity of services area.~~
- ~~2. Similarity of location;~~
- ~~3. Similarity of facilities; and~~
- ~~4. Similarity of service to be provided.~~

~~(c) If, at the time a competing application is filed there is already another competing application filed against the original application, the second competing application may be deemed to be competing against both the original application and the other competing application.~~

~~(d) The order in which competing applications will be placed on the agenda will be determined by the order in which the Letters of Intent were received in the Agency office.~~

(3) Simultaneous Review. Those persons desiring simultaneous review for a certificate of need for which a Letter of Intent has been filed shall file a Letter of Intent with the Agency and the original applicant, and publish the Letter of Intent simultaneously in a newspaper of general circulation, as those terms are defined in sub-paragraph (2)(d), above, in the same county as the original applicant within ten (10) days after publication by the original applicant. The Executive Director or his/her designee will determine whether applications are to be reviewed simultaneously.

(a) The applicant seeking simultaneous review shall, at the time the Letter of Intent is filed with the Agency, also file a verified statement certifying it has complied with the procedural requirements

for simultaneous review and evidence that the Notice was received by the Agency business office and the original applicant within ten (10) days after publication by the original applicant.

(b) In addition to the procedural requirements, the following factors may be considered by the Executive Director in determining whether the applications are to be reviewed as appropriate for simultaneous review:

1. Similarity of services area.
2. Similarity of location;
3. Similarity of facilities; and
4. Similarity of service to be provided.

(c) If, at the time an application is filed for simultaneous review, there is already another application filed for simultaneous review against the original application, the second application seeking simultaneous review may be simultaneously reviewed against both the original application and the other application seeking simultaneous review.

(d) The order in which applications filed for simultaneous review will be placed on the agenda will be determined by the order in which the Letters of Intent were received in the Agency office.

(e) Any application which is determined to not meet the criteria for a ~~“competing application”~~ “simultaneous review” shall be null and void. The application may be re-filed for a subsequent review cycle, but is subject to the same requirements as an original application.

(4) Applications.

(a) All applications must be filed in triplicate with the Agency within five (5) days after publication by the applicant, and must be accompanied by the filing fee. The date of filing shall be the actual date of receipt. If the last day for filing an application falls on a Saturday, Sunday, or State holiday, the application, to be timely, must be filed on the last preceding regular business day.

(b) Failure by the applicant to file an application within five (5) days after publication of the Letter of Intent in accordance with (a) above shall render the Letter of Intent, and hence the application, void.

(c) When an application is received at the Agency office, it must include an initial non-refundable filing fee, as provided elsewhere in these rules. Review for completeness shall not begin prior to the receipt of the filing fee.

(d) Each application that is accompanied by the applicable filing fee will be reviewed for completeness by Agency staff.

1. If it is deemed complete, the Agency will acknowledge receipt and notify the applicant that the review period will begin as of the date specified in the notification. Deeming complete means only that all questions and requests for information have been responded to in some reasonable manner. Deeming complete shall not be construed as validating the sufficiency of the information provided for the purposes of addressing the criteria under the applicable statutes, rules, and other guidelines.
2. If the application is incomplete, responses to requests for supplemental information by the staff must be completed by the applicant and filed at the Agency office within sixty (60) days of the written request by Agency staff. Failure of the applicant to meet this deadline will result in the application being considered withdrawn and returned to the contact person.

Resubmittal of the application must be accomplished in accordance with Rule 0720—3—.03 and requires an additional filing fee.

- (e) An application for certificate of need which has been deemed complete shall not be amended in a substantive way by the applicant during its review cycle. This Rule does not prohibit correction of clerical errors in the application.
- (5) Examination Filing Fee.
- (a) The amount of the initial fee shall be equal to \$2.25 per \$1,000 of the estimated capital expenditure involved, but in no case shall this fee be less than \$3,000 nor more than \$45,000.¹⁰
 - (b)¹¹ Any unpaid balance of litigation costs previously assessed against the applicant by the Tennessee Health Facilities Commission or the Tennessee Health Services and Development Agency, or any related entity of the applicant, ~~pursuant to T.C.A. §68-11-109(d)~~, may be offset against any filing fees paid. An application will not be deemed complete until the full filing fee, as well as such off set amounts, are paid in full.
 - (c) A final fee will be determined upon the Agency's receipt of the final project report. The amount of the final fee shall be the difference between the initial fee and the total fee based on actual final project costs, as such fee is calculated based on \$2.25 per \$1,000 of project costs, but in no case shall the total fee be less than \$3,000 nor more than \$45,000.¹²
- (6) Distribution of Applications. The Agency will promptly forward a copy of each application deemed complete to the Department of Health, or to the Department of Mental Health and Developmental Disabilities, and in doing so will fix at the date on which the review process established by statute and these regulation will commence.
- (7) Withdrawal of Applications. An application may be withdrawn at any time by the applicant.
- (8) Beginning of the Review Cycle. The review cycle for each application shall begin on the first day of the appropriate month after the application has been deemed complete by the staff of the Agency.
- (9) Reviewing Agencies' Actions on Applications.¹³
- (a) The Department of Health, or the Department of Mental Health/Mental Retardation, shall within seven (7) days from the receipt of a completed application give notice to the Agency of its receipt in writing. The appropriate review agency shall expeditiously review all applications in a consistent manner and conduct such studies and inquiries thereon as may be determined necessary by the appropriate review agency, by the Agency's rules, or upon request of the Agency, to enable it to make a report to the Agency. Applicants must comply promptly with all reasonable requests made by the appropriate reviewing agency, for additional information for the purpose of this review. Copies of said studies and all correspondence related to the application shall be forwarded to the Agency by the reviewing agency.
 - ~~(b) Requests for public hearings shall be received by the Department of Health within thirty (30) days of the date of publication of the Letter of Intent. All public hearings conducted by the Department pursuant to this part shall be held after giving written notification at least ten (10) days prior to the date of the hearing to the applicant and other affected persons. The Department shall allow any interested person the opportunity to be heard, and to present oral and written evidence at the hearing. A record of the hearings shall be made by the department and a transcript thereof shall be provided at the expense of any individual or group requesting one.~~¹⁴
 - (c) Within sixty (60) days (or thirty (30) days where the application is on the consent calendar), of the date fixed by the Agency pursuant to Rule 0720—3—.03(4), the reviewing agency shall file its official written report with the Agency. A copy of this report shall be forwarded by the reviewing agency to the applicant, and to any other person requesting one.

- (10) Reviewing Agency's Report to the Agency. The reviewing agency's report shall be made in a form prescribed by the Agency which shall address at a minimum each of the applicable criteria for certificate of need set forth in the statute, rules, and at the state health plan. The reviewing agency shall clearly set forth any planning methodologies, data bases, and resource materials utilized in making its findings. The reviewing agency will comply with all requests of the Agency in the specific application of the guidelines in the state health plan. The reviewing agency may include other information it deems appropriate and informative. The report shall address the following:
- (a) The criteria found in Agency Rules 0720—4.
 - (b) The current occupancy trends/utilization of facilities and/or services in the service area which are similar to those proposed by the applicant.
 - (c) A comparison of the project's cost of similar projects previously considered by the Agency in the preceding year.
 - (d) A verification of need methodologies provided by the applicant as well as provision of any additional methodologies that would further clarify the need for the project.
 - (e) The fiscal impact of the project on future state appropriations and/or expenditures.
 - (f) The availability of necessary professional and other staff to operate the proposed project.
 - (g) As assessment of the applicant's anticipated revenues and expenses.
 - (h) The applicant's compliance with the criteria found in Agency Rules 0720-4;
 - (i) A verification of the methodologies provided by the applicant to meet the criteria specified in (h), as well as identification of any additional methodologies that would further demonstrate compliance with the criteria;
 - (j) An assessment of the applicant's compliance with any applicable Guidelines for Growth;
 - (k) Any impact on future state appropriations and/or expenditures; and
 - (l) An analysis of the previous, current and proposed TennCare participation or non-participation of the applicant and any affiliate(s) involved with the project; to assist in such analysis, the TennCare Bureau shall prepare a report examining the TennCare participation of the applicant and any involved affiliate(s).¹⁵
- (11) An applicant may provide written supporting information to its application during the review cycle. Further, the applicant will have the right to respond in writing to the report made by the reviewing agency. The reviewing agency and the Health Services and Development Agency shall receive a copy of the applicant's response to the agency report not less than ten (10) days prior to the Health Services and Development Agency meeting.
- ~~(12) Notification of Agency Action. Written notice, including findings where appropriate, of the determination by the Agency granting or denying a Certificate of Need, or by deferring the application, will be transmitted to the applicant, the reviewing agency, and others upon written request.¹⁶~~
- (13) Holder of certificate of need. A certificate of need will normally be issued to the person who owns the real property of the institution or facility concerned, provided, however, that a certificate may be issued to:
- (a) The lessee or permittee of the property in cases where the property is not specifically designed for the provision of health care services and the lessor is not in the regular business of providing space for health care activities;
 - (b) The lessee of the property where the terms of the lease convey long-term control of the facility to the lessee;

- (e) A management company where the terms of the management agreement convey long-term control of the facility to the management company, and management company also has significant responsibility for implementing and completing the project; or
- (d) The person who directly provides equipment or facilities for health care activities when that person is not the owner of the property or facility.

Authority: T.C.A. § 68—11—1605; 68—11—1607; 68—11—1608; 68—11—1609; and 4—5—202.

0720—3—.04 EMERGENCY CERTIFICATE OF NEED¹⁷

- (1) Where an unforeseen event necessitates action of a type requiring a Certificate of Need and the public health, safety, or welfare would be unavoidable jeopardized by compliance with the standard procedures for application and granting of a Certificate of Need, the Agency may issue an emergency Certificate of Need.
- (2) An emergency Certificate of Need may be issued upon request of the applicant when the Executive Director and officers of the Agency concur, after consultation with the appropriate reviewing agency. Said Certificate is valid for a period not to exceed one hundred twenty (120) days: when the applicant has applied for a Certificate of Need under standard Agency procedures, an extension of the Emergency Certificate of Need may be granted.
- (3) For the purpose of this rule, the term “unforeseen event” means an event which could not be reasonably foreseen and which significantly affects the habitability of the facility or operation of the service including but not limited to fire, flood, acts of God, and the failure of fixed equipment such as heating, ventilating and air conditioning equipment, elevators, boilers, electrical transformers and switch gears, sterilization equipment, water supply and other utility connections

0720—3—.05 CONSENT CALENDAR

- (1) Each monthly meeting’s agenda will be available for both a consent calendar and a regular calendar.
- (2) In order to be placed on the consent calendar, the application must not be opposed by anyone having legal standing to oppose the application, and the Executive Director must determine that the application appears to meet the established criteria for granting a certificate of need. Public notice of all applications intended to be placed on the consent calendar will be given.
- (3) As to all applications which are placed on the consent calendar, the reviewing agency shall file its official report with the Agency within thirty (30) days of the beginning of the applicable review cycle.
- (4) If opposition by anyone having legal standing to oppose the application is stated in writing prior to the application being formally considered by the Agency, it will be taken off the consent calendar and placed on the next regular agenda. Any member of the Agency may state opposition to the application being heard on the consent calendar, and if reasonable grounds for such opposition are given, the application will be removed from the consent calendar and placed on the next regular agenda.
 - (a) For purposes of this rule, the “next regular agenda” means the next regular calendar to be considered at the same monthly meeting.
- (5) Any application which remains on the consent calendar will be individually considered and voted upon by the Agency.

Authority: T.C.A. §§68—11—1605; 68—11—1608; 4—5—202.

0720—3—.06 EXPIRATION, REVOCATION, AND MODIFICATIONS OF ISSUED CERTIFICATES

- (1) Prolonged certification periods and extensions of expiration dates of certificates are disfavored, and will be sparingly granted. Any request for a prolonged certification period must be clearly set forth in the application in order to be considered. A request for an extension of the expiration date must be made in writing to the Agency and filed prior to the first day of the month in which the application is to be considered by the Agency,¹⁸ and will be processed in accordance with policies established by staff.
- (2) Prolonged certification period. A prolonged certification period will be granted only where exceptional circumstances are shown to exist which make completion of the project within the time limits prescribed by statute unachievable using all reasonable means.
- (3) Extension of expiration date due to unforeseen occurrence. Extension of the expiration date of an issued certificate may be granted where some unforeseen and reasonably unavoidable occurrence causes a delay which makes completion of the project by the original expiration date unachievable using all reasonable means.
 - (a) Occurrences which may justify an extension of the expiration date include, without limitation, fire, flood, explosion, catastrophic weather conditions, riots or other civil disturbances, and similar occurrences. A court order enjoining the project, or otherwise significantly interfering with the completion of the project, may, in the discretion of the Agency, constitute grounds for an extension of the expiration date. Ordinarily, lack of adequate or accurate planning and/or financial difficulties will not justify an extension of the expiration date.
 - (b) All requests for extension of the expiration date must be filed in triplicate at the Agency office and be accompanied by a filing fee. The filing fee shall be an amount which bears the same ratio to the initial examination fee submitted with the application, as the requested extension of time bears to the original certification period.
- (4) Extension of expiration date due to appeal. In the event of a proper and timely appeal of the Agency's decision to grant a certificate of need, the certification period will be automatically extended, and the expiration date will be automatically stayed, during the pendency of the appeal.
 - (a) The time period of the extension/stay will be equal to the period of time beginning with the date the petition is received at the Agency's office, and ending with the effective date of the decision of the appellate court of last resort, or the expiration of the time period available for seeking further appellate review (where such appellate review is not sought), whichever occurs first.
 - (b) At the conclusion of the appellate process, as described in subparagraph (4)(a) above, a revised certificate of need, reflecting the new expiration date, may be issued upon request of the certificate holder.
- (5) In order to show substantial and timely progress in seeking an extension of the expiration date, the certificate holder must show that the project was on schedule and could reasonably have been completed by the expiration date, but for the unforeseen and unavoidable occurrence.
 - (a) By way of illustration, but not limitation, if construction had not proceeded beyond the footing stage at three months prior to the expiration date, substantial and timely progress would likely not be shown.
- ~~(6) The expiration date of a certificate of need occasioned by the completion of the action for which the certificate was granted will not be extended by the Agency.~~¹⁹
- (7) The Agency will conduct an annual review of progress of each project for which a certificate of need has been granted. The certificate holder shall timely respond to staff requests for information in connection with such progress reviews, and otherwise cooperate with staff in such progress reviews. The certificate holder must show that it is making substantial and timely progress in implementing the

project. In the absence of such a showing, the Agency may initiate proceedings to revoke the certificate of need.

- (8) Special corrections and revised certificates. Any issued certificate of need containing typographical errors or requiring similar clerical changes on its face, should be reported by the certificate holder and/or may be recalled by the Agency or staff. In the event of such non-substantive changes, or technical errors or omissions the Executive Director may issue a "revised" certificate in correct form. The certificate holder shall surrender the original certificate prior to its reissuance in corrected form.

- (a) Examples of errors and omissions and other nonsubstantive changes which may be made through a revised certificate include:

1. A typographical error;
2. A change in the name of an institution or facility;
 - (i) This refers only to a change in the "doing business as" name, not to a change of ownership. Any change of ownership occurring prior to licensure of a proposed new health care institution is covered in paragraph nine (9) of this rule.
 - (ii) A change of ownership of a health care institution occurring within two years of initial licensure requires notice to the Agency, but no revised or modified certificate of need will be issued.
3. An extension of the expiration date due to a completed appeal; and
4. Other non-substantive changes as approved by the Executive Director;

- (b) Except for changing the expiration date due to a completed appeal as provided above, a revised certificate pursuant to this subdivision shall not be construed as extending the expiration date.

- (9) Modifications and/or addendums to issued certificates. In the event a certificate holder wishes to make substantive changes relating to the scope, cost, or duration of the project, written request must be made to, and formally approved by, the Agency in its discretion.²⁰ If approved, such changes may be reflected in either the issuance of a modified certificate of need, or by the issuance of an addendum to the original certificate. If the request is denied, the Agency's decision is final, and no appeal shall be allowed.

- (a) Changes included within the provisions of this subdivision may include, but are not limited to, ²¹cost increases or decreases, downscaling or increasing²² the scope or square footage²³ of a project, requests for an extension of the expiration date and changes of ownership where allowed by law and Agency rules. Generally, such changes resulting in either a ten (10) percent increase or decrease shall be presumed substantive, though there will be instances where changes greater than ten (10) percent would not be substantial and instances where changes less than ten (10) percent would be substantial, depending upon the totality of the circumstances. In no event will any change in cost of less than \$1,000 be deemed a substantive cost modification.²⁴ In no event will any change which would independently require a certificate of need be considered for a modification or addendum. Multiple requests for modifications of a certificate of need, and such other modifications which in the discretion of the Agency would have significantly impacted public participation in the Agency's consideration of the original application, may be considered by the Agency as requiring a separate certificate of need.²⁵

1. Certain changes of ownership ("change of control"), prior to licensure constitutes the transfer of a certificate of need, and will render the certificate null and void, as provided in *T.C.A. §68—11—1620*.

In addition to the circumstances constituting a change of ownership ("change of control") as specified in *T.C.A. §68—11—1620*, the termination of interest of over 50% of the membership of a non-profit corporation constitutes a change of ownership/change of

control. If the change is made from a non-profit, membership corporation to a non-profit, non-membership corporation, there is no change of control if the boards of directors of the corporations are interlocking to the extent that there is no actual change of control of the corporate powers of the corporation which will hold the certificate of need.

- (b) Any certificate holder seeking a modification or addendum must make a formal request in writing to the Agency, in accordance with policies adopted by the Agency staff. Such written request must be accompanied by the appropriate supporting documentation justifying the requested modification. Simultaneously with the submission of such written request, the certificate holder shall also file written notice with all parties who sought simultaneous review, filed competing applications, or who opposed the original application.²⁶ Where an extension of the expiration date is sought, the request must be accompanied by the fee referred to elsewhere in these rules.
- (c) A change of site may not be approved through a modification or addendum; a separate certificate of need is required.
- ~~(d) The addition of a specialty to a certificate holder that is limited to either a single specialty or specific multiple specialties may not be approved through a modification or addendum; a separate certificate of need is required.~~²⁷

- (10) Any certificate holder seeking the removal of a condition which was placed on the certificate of need may make an application in writing to the Agency, in accordance with policies adopted by the Agency staff. At the time it makes such written application with the Agency, the certificate holder shall also file written notice with all parties who sought simultaneous review, filed competing applications, or who opposed the original application.²⁸ In order to show "good cause" for removing a condition, the certificate holder has the burden of showing that circumstances have significantly changed, which necessitate the removal of the condition. Mere disagreement or dissatisfaction with the condition will normally not be considered to be good cause for removing the condition.

- ~~(a) Application to the Agency for the addition of a specialty to an issued certificate that is limited to either a single specialty or specific multiple specialties shall be made by the filing of a new certificate of need application form, in addition to the requirements above, though removal of a condition is what is sought.~~²⁹

Authority: T.C.A. §§ 68—11—1605; 68—1—106; 68—11—1609; 68—11—1611; 68—11—1620; 4—5—202.

~~0720—3—.07—MEDICARE SKILLED NURSING FACILITY BED APPLICATIONS.~~³⁰

- ~~(1) Additional examination fee for consultant services. In addition to the initial examination filing fee described in Rule 0720—3—.03(5)(a), a Certificate of Need applicant for new Medicare skilled nursing facility beds as authorized by T.C.A. §§68—11—121 (f) shall pay an additional examination fee for the consultant services authorized therein.~~
- ~~(a) The application shall be accompanied with a \$5,000 deposit. Review for completeness of the application shall not begin prior to the receipt of both the initial filing fee and the \$5,000 deposit.~~
- ~~(b) The consultant services are charged at the hourly rate agreed upon between the Agency of the Department of Health and the consultant. If the total fee for such services is less than the \$5,000 deposit previously submitted by the applicant, the applicant shall be refunded the difference. If the total fee for such services is greater than the \$5,000 deposit, the applicant shall remit the difference to the Health Facilities Agency. Where the total fee is greater than the deposit, payment of the difference shall be made prior to the meeting at which the application is to be considered. A decision on the application shall be deferred by the Agency until payment of the entire fee is received.~~

¹ Jerry W. Taylor, Esq. of Farris Mathew Branan Bobango & Hellen made the following suggestion:

The approach of Subparagraph (2) of the referenced Rule, while laudable in giving maximum flexibility to the Agency, may not give sufficient guidance to the provider community. A better approach may be to specifically delineate the factors, the presence of which have traditionally negated a finding of a private professional practice. These factors appear to be:

(a) Ownership by a person other than a licensed health care practitioner, or by an entity which is not comprised entirely of licensed healthcare professionals (e.g., P.C., P.L.L.C., etc.), other than a physician practice management company;

(b) Use or availability of use of the facility or service by licensed healthcare professionals (or those under their supervision), who are not owners, partners, and/or employees of the CON holder/licensee;

(c) Services are billed under the name and/or provider number of any person or entity other than the professional practice CON holder and/or licensee. The exemption, if otherwise met, should not be lost due to billing by a third party billing company, if such third party billing company is doing so as an agent of the professional practice.

² Mr. John Wellborn of Development Support Group submitted the following comment:

In further considering how to improve this definition, the CON rules should respect the needs of physicians to enter into creative new organizational and clinical structures, in order to survive financially in an era of diminishing reimbursement, excessive insurance costs, and evolving surgical technology.

It is very difficult for any person to consistently evaluate over time the many factors now listed in this rule. Moreover, the present rule provides no clear guidance to the public, which seems essential to a good rule.

Perhaps the Agency could relate the private practice exemption to the definition suggested for ASTC in this letter. It is objectively ascertainable whether procedures are reimbursable with a facility or technical fee, and whether they are being done with general anesthesia. If neither factor is present, the enterprise can be considered the realm of private practice regardless of who employs who, how it is marketed and "controlled", etc.

³ Commissioner Flowers made the following suggestion:

To ensure that the public has adequate notification of substantive amendments and other proposed changes to approved CONs, I would propose that we add a new subsection to this rule:

() Substantive amendments filed by an applicant as defined in Rule 0720-2-.01 (26).

Commissioner Flowers has recommended language requiring notification of the public when modifications to issued certificates are requested, and such language has been added to 0720-3-.06(9), which addresses requests for modifications to issued certificates.

⁴ Citation to new statutory provision.

⁵ Agency Staff proposed the deletion to provide greater flexibility.

⁶ Commissioner Flowers has commented that the proposed rule should reference instead this Agency's definition contained in Tenn. Code Ann. § 68-11-1620 and Tenn. R. & Reg. § 0720-3-.06 (9)(a). Therefore, Agency Staff proposed that the such language be deleted, with "change or ownership/control" only being defined by the statute and elsewhere in the rule. No special mention need be made in 0720-3-.02(5).

⁷ Agency Staff proposed that 0720-3-.02(6) be deleted in its entirety because registration of medical equipment is provided for in a comprehensive manner by the new statute.

⁸ T.C.A. 2-1-117 defines "newspaper of general circulation." The Agency's definition closely follows the statutory definition, except in this respect. Therefore, the amendment is proposed by Agency Staff.

⁹ Due to different terminology found in the new statute (what was termed "competing applications" is now termed "simultaneous review."), Agency Staff proposed that 0720-3-.03(3)(a)(b)(c) and (d) be deleted in their entirety, and be replaced by new language.

¹⁰ The maximum fee was last raised in 1993, from \$30,000 to \$45,000.

¹¹ The amendments to this subsection were proposed by Agency Staff because of the new statutory reference and to encompass debts owed to both the Commission and the Agency re. the certificate of need process.

¹² Agency Staff proposed that the maximum fee be reiterated to provide greater clarity.

¹³ Agency Staff had proposed that 0720-3-.03(9) be deleted in its entirety because the new statute provides comprehensively regarding reviewing agencies' reports. Such proposal has been withdrawn due to feedback expressing discomfort with the proposed deletion by Commissioner Flowers and other interested parties.

¹⁴ Agency Staff proposed the amendment because the old statute required the Department of Health to conduct such hearings, whereas the new statute does not.

¹⁵ Subsections (h) – (l) were recommended by Commissioner Flowers "[i]n order to comply with the statutory directive in T.C.A. § 68-11-1608 (a) that TennCare participation be analyzed by the reviewing agencies. . ."

¹⁶ Agency Staff has proposed the deletion because T.C.A. § 68-11-1609(f) provides for such in virtually identical language.

¹⁷ Agency Staff had proposed the deletion because the old statute specifically provided for emergency certificates of need. Agency Staff and interested parties have expressed a desire to have the ability to grant certificates of need on an emergency basis, and the new statute does reference the Executive Director's ability to establish an emergency calendar. Therefore, the proposed deletion is withdrawn.

¹⁸ Agency Staff proposed the amendment to establish a uniform standard to enable Agency staff to provide adequate notice of such requests to the Agency prior to its meeting. Untimely, last minute requests are not entirely uncommon.

¹⁹ Agency Staff proposed that 0720-3-.06(6) be deleted in its entirety because 0720-3-.06 does not seem necessary, and has been used to support the argument that one can avoid the denial of a CON at the end of the appeal process by merely completing the project before the completion of the appeal process. While the argument has been denied by an Administrative Judge, there's no need to encourage it. Commissioner Flowers has commented that it's a good idea to delete this language.

²⁰ Commissioner Flowers made the following suggestion:

Rule 0720-2-.01 (26) "Substantive amendment" definition. I would suggest that we reference modifications to approved CONs which may rise to this level and require a new CON (discussed further below). I suggest that we rewrite the definition as follows (additions are underlined):

(26) "Substantive amendment" as used in T.C.A. § 68-11-1607 means any amendment or proposed modification to an approved CON as defined in Rule 0720-3-.06 (9)(d), which has the effect of increasing the number of beds, square footage, cost, or other elements which are reasonably considered in the discretion of the Agency to be integral components of the original application. A reduction of the above referenced components may be considered a substantive amendment if the amendment and supporting documentation are not received by the staff and Agency in a timely manner, necessary to allow the Agency to make an informed decision. Nothing in this rule shall be interpreted as limiting the Agency's authority to approve or deny all or part of any given application.

By statute, a "substantive amendment" is made to an application for a certificate of need, not an issued certificate. Therefore, Agency Staff has attempted to incorporate the substance of Commissioner Flowers' suggestions in the section of the Agency's Rules that addresses changes to issued certificates [0720-3-.06(9)].

²¹ Id.

²² Id.

²³ Id.

²⁴ It is not uncommon for changes to be made to project plans after a CON has been granted. The question is often posed to the Agency and its staff: to what extent may changes be made before they are so substantial as to necessitate a modification of the CON? Agency Staff had proposed 15% as a presumption that would not foreclose a change of either a greater or lesser percentage requiring modification, it would provide a good "rule of thumb." The 15% figure was based upon the North Carolina Rules. Ms. Weaver questioned the 15% figure, and proposed 10% instead.

²⁵ Suggested by Commissioner Flowers.

²⁶ Commissioner Flowers suggested language requiring additional notification for a modification of a certificate of need. Mr. Duckett added that requiring publication may be a good idea too, because it is conceivable that there are parties who did not object to the project as proposed in the original application, but would find the proposed modification objectionable.

²⁷ See endnote 29, below.

²⁸ Commissioner Flowers suggested language requiring additional notification, as with the section above.

²⁹ Commissioner Flowers had recommended the addition of the following subsection to 0720-3-.06(9):

(d) The addition of a specialty to a single specialty facility shall not be considered a modification but rather a substantive amendment which would independently require a certificate of need application. Multiple requests for modifications, and such other modifications which in the discretion of the Agency would have significantly impacted public participation in the original CON process, may be considered by the Agency as substantive amendments which would independently require a certificate of need application.

Dan H. Elrod, Esq. expressed concern that requiring an additional certificate of need, by rule, may lack statutory authority, and therefore worked with Agency Staff to craft language that would encompass the spirit of Commissioner Flowers' suggestion, but in the form of a modification of the certificate of need.

³⁰ Agency Staff proposed that the Rule be deleted in its entirety because the Agency no longer utilizes such professional consulting fees.